

Active Screening for Carbapenemases in **2 Hours** by Real-Time PCR

KPC

OXA-48

VIM

NDM



Rapid Molecular Detection of Carbapenemase-Producing *Enterobacteriaceae* (CPE) – Why Now?

- Invasive infections associated with CPE have mortality rates as high as 50% or more^{1,2}
- CPE are increasing at an alarming speed and can spread rapidly in healthcare settings and in the community if not controlled^{1,3}
- CPE of all types may appear susceptible to carbapenems^{4,5}
- Carbapenem resistance may be due to non-carbapenemase mechanisms with low risk of transmission^{1,4}
- Early detection by active screening of high-risk patients is strongly recommended to prevent the further spread of CPE^{1,2,4}

Check-Direct CPE: Your First Step to Control CPE

Easy to use

Performed directly from rectal swabs

Quick

Active screening results in just 2 hours:

- Enables prompt initiation of infection control measures
- Shortens the duration of pre-emptive isolation

Results you can trust

Minimize the impact of CPE in your healthcare facility:

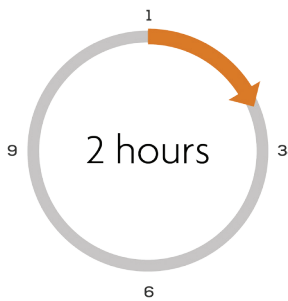
- Reduce the risk of transmission to other patients
- Avoid unnecessary isolation of negative patients and optimize antibiotic use
- Information on the carbapenemase type can help exclude outbreaks



Speed

Check-Direct CPE

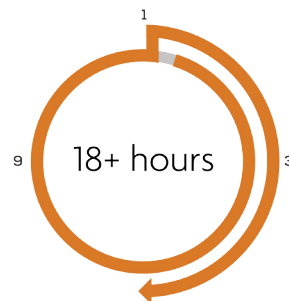
Clear-cut results in just 2 hours



- ✓ Definitive result
- ✓ Genotypic confirmation
- ✓ Differentiation of carbapenemase types

Conventional culture

Requires at least 18 hours and further confirmatory testing



- ✗ Presumptive result
- ✗ No confirmation
- ✗ No differentiation of carbapenemase types

Versatility

Identify CPE carriers directly

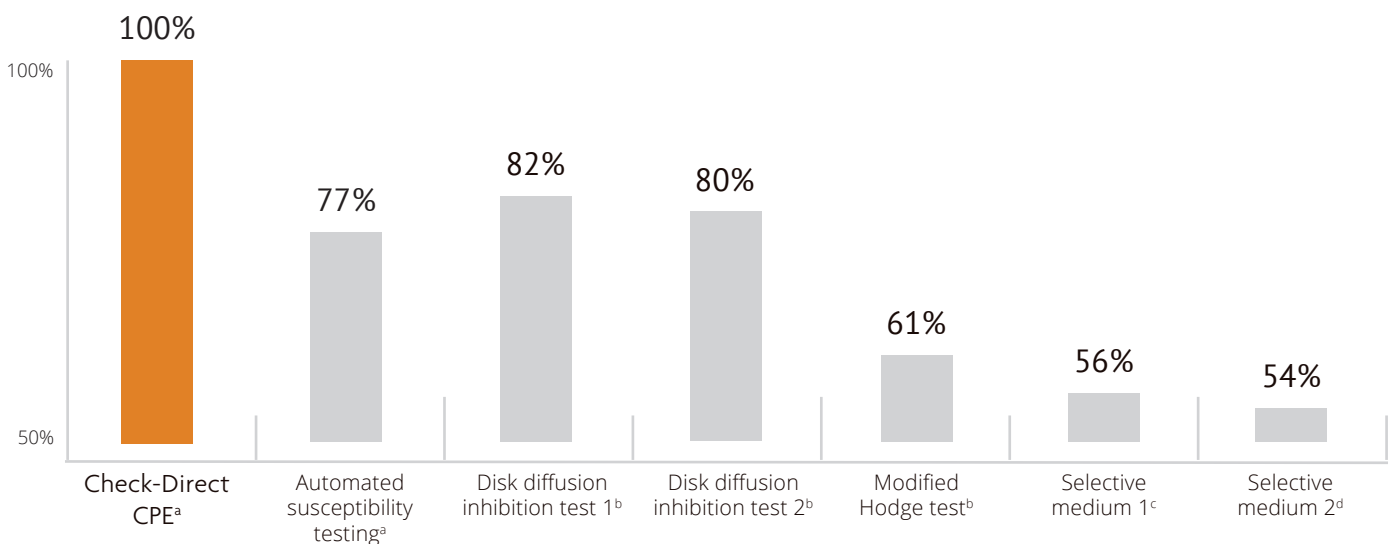


Confirm suspected CPE from routine clinical cultures



Sensitivity

Performance comparisons*



a: Internal performance data of Check-Direct CPE vs. automated susceptibility testing using 91 clinical isolates confirmed to be positive for KPC, OXA-48, VIM or NDM by sequencing; b: Doyle D et al. JCM 2012; c: Wilkinson KM et al. JCM 2012; d: Day KM et al. JAM 2013.

*Test performance assessments based on independent peer reviewed publication. Performance assessments do not represent "head" to "head" comparisons.

Assay Specifications: Check-Direct CPE

Specimen	Rectal swab	Culture
Carbapenemase target genes*	KPC, OXA-48, VIM, NDM	
Sample preparation	NucliSENS® easyMAG®	Crude extraction
Amplification and Detection	ABI 7500, LightCycler® 480 system I&II	ABI 7500, CFX96™, LightCycler® 480 system I&II, Rotor-Gene Q
Controls included	Positive controls: KPC, OXA-48, VIM, NDM Negative control Internal control	
Limit of detection	< 5 copies/PCR reaction for KPC, OXA-48, VIM and NDM	
Analytical reactivity	Tested with: <ul style="list-style-type: none"> • 19 different strains of KPC • 25 different strains of OXA-48 • 17 different strains of NDM • 34 different strains of VIM 	
Analytical specificity	No positive results when tested against 87 non-carbapenemase producers	
Result	• KPC • OXA-48 • VIM/NDM	

KPC-2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25; OXA-48, 48b, 162, 163, 181, 204, 232, 244, 245, 370; VIM- 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47; NDM-1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16.

Ordering Information

Catalog no.	Description
18-0080	Check-Direct CPE kit, 48 reactions

EU: For *in vitro* Diagnostic Use.
 US: For Research Use Only. Not for use in diagnostic procedures.

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Check-Points Health B.V.
 Binnenhaven 5
 6709 PD Wageningen
 The Netherlands

Tel: +31 317 453 908
 Fax: +31 317 210 147
 info@check-points.com

US representative:
 Vijai K. Pasupuleti, Ph.D
 IMDS
 1436 Fargo Blvd.
 Geneva IL, 60134

Tel: +1 630 673 6868
 info@theimds.com